

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION**

MARJORIE HELEN LEWIS and)	
Husband, RONALD LEWIS)	
)	
Plaintiffs,)	
)	
v.)	CIVIL ACTION NO: 2:12-cv-00115
)	
NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. d/b/a NEW)	
ENGLAND COMPOUNDING CENTER,)	
AMERIDOSE, LLC, MEDICAL SALES)	
MANAGEMENT, INC., BARRY J.)	
CADDEN, GREGORY A.)	
CONIGLIARO, DOUGLAS A.)	
CONIGLIARO, LISA CONIGLIARO)	
CADDEN, CARLA CONIGLIARO, and)	
GLENN A. CHIN,)	
)	
Defendants.)	

ANSWER OF CARLA R. CONIGLIARO

Defendant Carla R. Conigliaro ("Defendant"), by and through undersigned counsel, hereby answers Plaintiffs' Complaint as follows:

1. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1.

2. Defendant admits that New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), at relevant times, did business as "New England Compounding Center." Defendant also admits that NECC is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham, Massachusetts. Defendant further admits that, at or about the time this action was commenced, Gregory Conigliaro was the registered agent for NECC. The remaining allegations in Paragraph 2 call for

legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

3. Defendant admits that Ameridose, LLC is a Massachusetts limited liability company with a principal place of business located at 205 Flanders Road, Westborough, Massachusetts. Defendant further admits that, at or about the time this action was commenced, the registered agent for Ameridose, LLC was Gregory Conigliaro. The remaining allegations of Paragraph 3 call for legal conclusions for which no response is required.

4. Defendant admits that Medical Sales Management, Inc. is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham, Massachusetts. Defendant further admits that, at or about the time this action was commenced, the registered agent for Medical Sales Management, Inc. was Gregory Conigliaro. The remaining allegations in Paragraph 4 call for legal conclusions for which no response is required.

5. Defendant admits that, at or about the time this action was commenced, Barry J. Cadden was a resident of Massachusetts, as well as a shareholder, officer, and director of NECC and a part owner of Ameridose, LLC. The remaining allegations in Paragraph 5 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

6. Defendant admits that, at or about the time this action was commenced, Gregory Conigliaro was a resident of Massachusetts, as well as a shareholder, officer, and director of NECC. Defendant further admits that, at or about the time this action was commenced, Gregory Conigliaro was a manager and part owner of Ameridose. The remaining allegations in Paragraph 6 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

7. Defendant admits that, at or about the time this action was commenced, Douglas Conigliaro was a resident of Massachusetts, as well as a shareholder, officer, and director of Medical Sales Management. The remaining allegations in Paragraph 7 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

8. Defendant admits that, at or about the time this action was commenced, Lisa Conigliaro Cadden was a resident of Massachusetts, as well as a shareholder and director of NECC and a part owner of Ameridose. The remaining allegations in Paragraph 8 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

9. Defendant admits that, at or about the time this action was commenced, she was a resident of Massachusetts, as well as a shareholder and director of NECC. Defendant further admits that, at or about the time this action was commenced, she was a part owner of Ameridose. The remaining allegations in Paragraph 9 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

10. Defendant admits that, at or about the time this action was commenced, Glenn A. Chin was a resident of Massachusetts. The remaining allegations in Paragraph 10 call for legal conclusions for which no response is required. However, to the extent they are to be construed against Defendant, they are denied.

11. Defendant admits that from time to time, NECC compounded and dispensed a preparation known as methylprednisolone acetate ("MPA"). Defendant is not required to respond to the remaining allegations of Paragraph 11 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

12. Defendant is not required to respond to the allegations of Paragraph 12 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO FACTUAL ALLEGATIONS

13. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13 pertaining to Plaintiff Marjorie Helen Lewis's medical condition or treatment. Defendant is not required to respond to the remaining allegations of Paragraph 13 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

14. The statements of the U.S. Food and Drug Administration speak for themselves. The remaining allegations in Paragraph 14 call for legal conclusions for which no response is required. However, to the extent such allegations may be construed against Defendant, they are denied.

15. Defendant is not required to respond to the allegations of Paragraph 15 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

16. Defendant is not required to respond to the allegations of Paragraph 16 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

17. Defendant is not required to respond to the allegations of Paragraph 17 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

18. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18 relating to Plaintiff Marjorie Helen Lewis's treatment. Defendant is not required to respond to the allegations of Paragraph 18 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

19. Defendant is not required to respond to the allegations of Paragraph 19 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

20. The statements of the Center for Disease Control, U.S. Food and Drug Administration, and the Commonwealth of Massachusetts Office of Health and Human Services speak for themselves, but to the extent a responsive pleading is necessary, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20.

21. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21 relating to Plaintiff Marjorie Helen Lewis' injuries or damages or her husband's damages. Defendant is not required to respond to the allegations of Paragraph 21 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO ALLEGED WRONGS

22. Defendant admits that, at or about the time this action was commenced, she was a shareholder and director of NECC. Defendant further admits that, at or about the time this action was commenced, she was a part owner of Ameridose and Medical Sales Management. Defendant is not required to respond to the allegations in Paragraph 22 that are not directed to

her. Defendant is not required to respond to the allegations in Paragraph 22 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

23. Defendant admits that, at or about the time this action was commenced, she was a shareholder and director of NECC. Defendant further admits that, at or about the time this action was commenced, she was a part owner of Ameridose and Medical Sales Management. Defendant is not required to respond to the allegations in Paragraph 23 that are not directed to her. Defendant is not required to respond to the allegations in Paragraph 23 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

24. Defendant is not required to respond to the allegations of Paragraph 24 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

25. Defendant is not required to respond to the allegations of Paragraph 25 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

26. Defendant is not required to respond to the allegations of Paragraph 26 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

27. Defendant is not required to respond to the allegations of Paragraph 27 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

28. Defendant is not required to respond to the allegations of Paragraph 28 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- a. Defendant is not required to respond to the allegations of Paragraph 28(a) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- b. Defendant is not required to respond to the allegations of Paragraph 28(b) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- c. Defendant is not required to respond to the allegations of Paragraph 28(c) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- d. Defendant is not required to respond to the allegations of Paragraph 28(d) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- e. Defendant is not required to respond to the allegations of Paragraph 28(e) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- f. Defendant is not required to respond to the allegations of Paragraph 28(f) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- g. Defendant is not required to respond to the allegations of Paragraph 28(g) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- h. Defendant is not required to respond to the allegations of Paragraph 28(h) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- i. Defendant is not required to respond to the allegations of Paragraph 28(i) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- j. Defendant is not required to respond to the allegations of Paragraph 28(j) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

29. Defendant is not required to respond to the allegations of Paragraph 29 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPONDING TO ALLEGED INJURIES AND DAMAGES

30. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30 pertaining to Plaintiff Marjorie Helen Lewis's medical treatment, medical condition, or financial losses or Plaintiff Ronald Lewis's mental anguish. Defendant is not required to respond to the remaining allegations in Paragraph 30 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

RESPOND TO WHEREFORE CLAUSE

WHEREFORE Defendant denies entitlement to the relief requested in the Complaint.

JURY DEMAND

Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to the Defendant. To the extent any of the following is available and may apply, notice hereby is given of the following:

1. The Complaint fails to state a claim or cause of action cognizable in law or equity.
2. The Complaint fails to allege a cognizable claim for breach of any applicable standard of care.
3. The Complaint may be barred, in whole or in part, by applicable statutes of limitation and/or repose.
4. Standing to sue has not been properly alleged and may be lacking on all or some of the claims.
5. This action may be dismissed and/or transferred under the doctrine of forum non conveniens.
6. No compensable injury has been sufficiently stated or proven.
7. The Complaint fails to sufficiently identify a preparation compounded or dispensed by the Defendant.
8. The Complaint fails to adequately allege injuries or compensable damages that may or may not have been proximately caused by the Defendant.

9. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of the Defendant.

10. The injuries or damages alleged may have been caused or contributed to by pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses.

11. The injuries or damages alleged may have been caused or contributed to by an idiosyncratic reaction to any compounded or dispensed preparation.

12. The preparation alleged to have caused injury or damage was dispensed and compounded in accordance and consistent with the state of the art in the industry.

13. The alleged injuries or damages may have been caused or contributed to by known risks inherent in certain medical procedures, and that otherwise are open and obvious, or that voluntarily were undertaken, with full knowledge and consent. Such risks therefore may have been assumed and accepted through consenting and engaging in said medical procedures.

14. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

15. The preparations compounded and dispensed were intended to be used and administered only by licensed health care practitioners in the care and treatment of their patients. Such licensed health care practitioners were knowledgeable, learned intermediaries and sophisticated users in treating patients and performing medical procedures.

16. The alleged injuries or damages may have been caused by the unforeseeable misuse, abuse, or inappropriate handling of the preparation by others, which was unforeseeable to the Defendant.

17. The preparation may have been modified, altered, or changed from the condition in which it originally was compounded and dispensed, which modification, alteration, or change may have caused or contributed to the alleged injuries or damages.

18. Claims under applicable state law fail to state any claim upon which relief can be granted.

19. To the extent that comments (g), (h), (i), (j) and (k) of Section 402A of the Restatement (Second) of Torts and Comment (b) of Section 6 of the Restatement (Third) of Torts are applicable, such provisions may be relied on in defense of this action.

20. Damages, if any, have not been appropriately mitigated.

21. The injuries or damages alleged may have been caused in whole or in part by the purported contributory negligence and/or culpable conduct of others and not as a result of any conduct on the part of the Defendant. Recovery, if any, should be limited or reduced in proportion to the parties' purported comparative fault and in accordance with applicable state law.

22. Any alleged liability of the Defendant is limited to the allowable percentage of alleged culpability found and should be further limited by virtue of the fault of other parties or entities (appearing and non-appearing, named and un-named) and in accordance with applicable state law.

23. The alleged injuries or damages alleged may be attributable to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each cause of the harm sustained, if any.

24. The claim should be diminished in whole or in part by any amount paid or fairly allocable to any party that has settled or may settle.

25. Any verdict or judgment must be reduced by those amounts that have or will, with reasonable certainty, replace or indemnify, in whole or in part, for any past or future claimed loss, including from any collateral sources such as insurance, disability, social security, worker's compensation, or employee benefit programs.

26. Any liability for non-economic loss is limited in accordance with the alleged relative culpability of all persons or entities contributing to the total liability for alleged non-economic loss, including named parties and others over whom personal jurisdiction could have been obtained with due diligence.

27. Applicable state and federal laws prohibit a finding of personal liability against any individual Defendant.

28. The claims are barred, in whole or in part, based on a balancing of risk and utility factors.

29. The alleged damages were not caused by any failure to warn.

30. No warranty, express or implied, was made.

31. Claims for breach of express or implied warranty are barred for lack of privity.

32. Claims for breach of warranty are barred for lack of reliance.

33. Notice was not received of any claimed breach of warranty, including any notice potentially required under the Uniform Commercial Code, Section 2-607(e), or by any other applicable federal or state law.

34. Punitive damages are barred because applicable procedures fail to provide specific limits or standards as to the amount of any such award.

35. Punitive damages are barred because applicable procedures do not provide sufficient notice of the type of conduct on which an award of punitive damages may be based.

36. Punitive damages are barred because applicable procedures fail to provide clear, consistent standards for appellate review of an award of punitive damages.

37. Punitive damages are barred because applicable procedures may allow for the consideration of inappropriate evidence, such as wealth, in assessing punitive damages.

38. An award of punitive damages as alleged would violate one or more of the protections provided by the United States Constitution and/or any other applicable state statute or constitution or law.

39. Defendant relies on all applicable defenses afforded it under the Tennessee Products Liability Act of 1978, Tenn. Code Ann. § 29-28-101, et seq.

40. Other defenses may be relied on, including any that may be asserted by others, or that may become available or apparent during proceedings in this case. The right to amend and incorporate such defenses hereby is reserved.

WHEREFORE, Defendant prays judgment of this Court

- a. dismissing the Complaint against her, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Respectfully submitted,

BAKER, DONELSON, BEARMAN, CALDWELL
& BERKOWITZ, PC

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Date: February 11, 2013

Attorneys for Carla Conigliaro

CERTIFICATE OF SERVICE

I, Carrie W. McCutcheon, hereby certify that on this 11th day of February, 2013, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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